




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

FROM: Warren E. Lux, M.D. 
EPA Human Subjects Research Review Official (8105R)

TO: Patti Lynne Tyler
Science Advisor, EPA Region 8

SUBJECT: Human Subjects Research Determination

DATE: May 17, 2007

I have reviewed the project cited below according to the definitions found at EPA Regulation 40 CFR 26.102(d)&(f) and have determined that it does not qualify as research involving human subjects by virtue of the fact that it is acquiring data about the environment, particularly the air, and not about the humans themselves, and that the data obtained are within the scope of public health practice and are not designed to develop or contribute to generalizable knowledge. Accordingly, it is not subject to the requirements found in EPA Order 1000.17 Change A1 (**Policy and Procedures on Protection of Human Research Subjects**) or EPA Regulation 40 CFR 26 (**Protection of Human Subjects**).

PHREP #: E07-0016

Project Title: *Activity-Based Outdoor Air Sampling, Operable Unit 4, Libby, Montana, Superfund Site*

EPA Team Leader: Paul Peronard

CC: Paul Peronard
Wendy O'Brien